

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of:  
Bret BERNER et al.

Confirmation No.: 5481

Serial No.: 10/024,932

Group Art Unit: 1615

Filing Date: December 18, 2001

Examiner: Edward J. WEBMAN

Title: GASTRIC RETENTIVE ORAL DOSAGE FORM WITH RESTRICTED DRUG RELEASE IN  
THE LOWER GASTROINTESTINAL TRACT

**RESUBMITTED INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia

Sir:

Further to the Examiner's request in the Office Action of September 29, 2003, the Information Disclosure Statement of December 18, 2001, is resubmitted per the Examiner's request. In the Office Action, the Examiner indicated that the cited references were not available to the Examiner. As the cited references are provided with this paper, applicants respectfully request that the Examiner review and make of record the references identified below.

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U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,695,467	9/22/87	Uemura et al.
4,910,021	3/20/90	Davis et al.
5,002,772	3/26/91	Curatolo et al.
5,007,790	4/16/91	Shell
5,425,950	6/20/95	Dandiker et al.
5,582,837	10/10/96	Shell
5,738,874	4/14/98	Conte et al.
5,783,212	7/21/98	Fassihi et al.
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5,891,474	4/6/99	Busetti et al.
5,945,125	8/31/99	Kim
5,972,389	10/26/99	Shel
6,027,748	2/22/00	Conte et al.
6,093,420	7/25/00	Baichwal
6,120,803	9/19/00	Wong et al.
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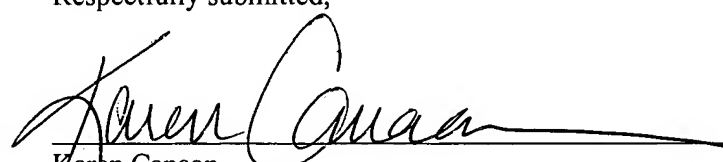
NONPATENT DOCUMENTS
Katori et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

The attached return post-card indicates that the cited references were mailed along with the Information Disclosure Statement and PTO-1449 on December 18, 2001; accordingly, applicants submit that this resubmission of the Information Disclosure Statement of December 18, 2001, should not be subject to a fee. Nevertheless, if the Office deems that a fee is necessary, then the Office is authorized to charge the appropriate fee to Deposit Account No. 18-0580.

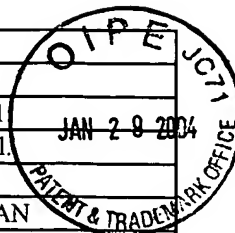
Respectfully submitted,

By:

  
Karen Canaan  
Registration No. 42,382

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Substitute for form 1449A/PTO  <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(use as many sheets as necessary)</p>				<b>Complete if Known</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/024,932</td> </tr> <tr> <td>Filing Date</td> <td>December 18, 2001</td> </tr> <tr> <td>First Named Inventor</td> <td>Bret BERNER et al.</td> </tr> <tr> <td>Art Unit</td> <td>1615</td> </tr> <tr> <td>Examiner Name</td> <td>Edward J. WEBMAN</td> </tr> <tr> <td>Attorney Docket Number</td> <td>3100-0001.20</td> </tr> </table>		Application Number	10/024,932	Filing Date	December 18, 2001	First Named Inventor	Bret BERNER et al.	Art Unit	1615	Examiner Name	Edward J. WEBMAN	Attorney Docket Number	3100-0001.20
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4,748,023	5/31/88	Tamás et al.
4,786,503	11/22/88	Edgren et al.
4,839,177	6/13/89	Colombo et al.
4,851,232	7/25/89	Urquhart et al.
4,865,849	9/12/89	Conte et al.
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5,213,808	5/25/93	Bar-Shalom et al.
5,232,704	8/3/93	Franz et al.

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5,458,887	10/17/95	Chen et al.
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5,651,985	7/29/97	Penners et al.
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5,688,776	11/18/97	Bauer et al.
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5,916,595	6/29/99	Chen et al.
6,033,685	3/7/00	Qiu et al.
6,207,197	3/27/01	Illum et al.
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6,368,628	4/9/02	Seth
6,451,808	9/17/02	Cowles
6,488,962	12/3/02	Berner et al.
2001/0018070	8/30/01	Shell et al.
Serial No. 09/425,491	Filed 10/22/99	Shell et al.
Serial No. 10/029,134	Filed 10/25/01	Gusler et al.
Serial No. 10/045,823	Filed 11/6/01	Shell et al.
Serial No. 10/066,146	Filed 2/1/02	Lim et al.
Serial No. 10/152,914	Filed 5/20/02	Fara et al.

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EP 0795324 A2	9/17/97	Europe
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WO 98/55107 A1	12/10/98	PCT
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FOREIGN PATENT DOCUMENTS		
Document No.	Publication Date	Country
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Abrahamsson, et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> <u>10</u> (5):709-714.
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Gusler et al. (June 2001), "Pharmacokinetics of Metformin Gastric-Retentive Tablets in Healthy Volunteers," <i>The Journal of Clinical Pharmacology</i> <u>41</u> (6):655-661.
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Hwang et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> <u>15</u> (3):243-284.
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Korsmeyer et al. (1983), "Mechanisms of Solute Release from Porous Hydrophilic Polymers," <i>International Journal of Pharmaceutics</i> <u>15</u> :25-35.
Maggi et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> <u>195</u> :229-238.
Rao et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> <u>48</u> :1-13.
Reynolds et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> <u>87</u> (9):1115-1123.
Siepmann et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> <u>16</u> (11):1748-1756.
Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> <u>85</u> (2):170-173.

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Respectfully submitted,

By:

  
Karen Canaan  
Registration No. 42,382

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	DO	Siepmann et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> <u>16</u> (11):1748-1756.	
	DP	Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> <u>85</u> (2):170-173.	

<b>Examiner Signature</b>		<b>Date Considered</b>	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.